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APPEAL BRIEF

Applicant	:	George P. Teitelbaum et al.
App. No	:	10/689,199
Filed	:	October 20, 2003
For	:	FORMABLE ORTHOPEDIC FIXATION SYSTEM WITH CROSS LINKING
Examiner	:	James L. Swiger III
Art Unit	:	3733

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Sir:

In accordance with the Notice of Appeal filed February 28, 2007, Applicant submits this Appeal Brief.

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I. REAL PARTY IN INTEREST

The real party in interest is SDGI Holdings, Inc., the assignee of record.

II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-25, 31, 32, and 36-52 have been canceled. Claims 26-30 and 33-35 have been finally rejected in the Final Office Action dated November 30, 2006. Claims 26-30 and 33-35 are being appealed.

IV. STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 26

26. A subcutaneously assembled in place orthopedic construct, comprising:
a first bone anchor comprising a distal end and a proximal end, the proximal end including a head with a portal extending therethrough;
a second bone anchor comprising a distal end and a proximal end, the proximal end including a head with a portal extending therethrough;
a first support structure, configured to extend through the portals in the first and second bone anchors;
a second support structure, configured to be attached to the spine; and
a cross bar, which connects the first support structure to the second support structure to form an orthopedic construct;
wherein the cross bar is attached to the first and second support structures subcutaneously; and
wherein at least the cross bar comprises a media that is hardenable while the support structure is positioned within the body of a patient.

Claim 26 recites a subcutaneously assembled in place orthopedic construct comprising a first bone anchor, a second bone anchor, a first support structure attached to the first and second bone anchors, a second support structure attached to the spine and a cross bar attached to the first and second support structures (Specification, page 30 line 28 to page 31 line 27; Figures 34 and 35, elements 208, 222a, 222b and 222c). The cross bar is attached to the first and second support structures subcutaneously and comprises a media that is hardenable (Specification, page 31 line 21 to page 32 line 8; Figure 35, elements 222a, 222b and 222c).

FIG. 34

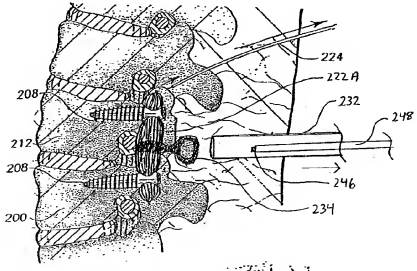
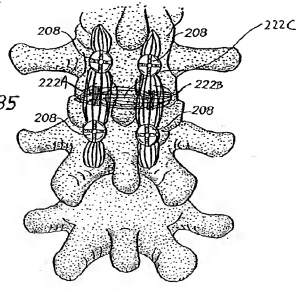

224
222A
232
248
208
212
208
246
200
234

FIG. 35


208
208
222C
222A
222B
208
208

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. The rejection of Claims 26-27 and 30-31 under 35 U.S.C. 103(a) as being unpatentable over Stalcup et al. (U.S. Patent No. 6,336,930) in view of Fournet-Fayard et al. (U.S. Patent No. 5,486,174).

B. The rejection of Claims 28-29 under 35 U.S.C. 103(a) as being unpatentable over the combination of Stalcup et al. '930 and Fournet-Fayard et al. '174 and further in view of Gelbard (U.S. Patent No. 5,397,363).

C. The rejection of Claims 33-34 under 35 U.S.C. 103(a) as being unpatentable over the combination of Stalcup et al. '930 and Fournet-Fayard et al. '174 and further in view of Boyce et al. (U.S. Patent No. 5,899,939).

D. The rejection of Claim 35 under 35 U.S.C. 103(a) as being unpatentable over the combination of Stalcup et al. '930 and Fournet-Fayard et al. '174 and further in view of Tormala et al. (U.S. Patent No. 5,084,051).

VII. ARGUMENT

A. The rejection of Claims 26-27 and 30-31 under 35 U.S.C. 103(a) as being unpatentable over Stalcup et al. (U.S. Patent No. 6,336,930) in view of Fournet-Fayard et al. (U.S. Patent No. 5,486,174).

Claim 26 recites, in part, a "subcutaneously assembled in place orthopedic construct, comprising: a first bone anchor comprising a distal end and a proximal end, the proximal end including a head with a portal extending therethrough; a second bone anchor comprising a distal end and a proximal end, the proximal end including a head with a portal extending therethrough; a first support structure, configured to extend through the portals in the first and second bone anchors; a second support structure, configured to be attached to the spine." Claim 26 was rejected over the combination of Stalcup and Fournet-Fayard.

Fournet-Fayard discloses a pedicle screw 3 with a head that is open along its transverse axis. The head is configured to receive an elongated rod 4, which extends through the opening in the head. See Figure 3 reproduced below.

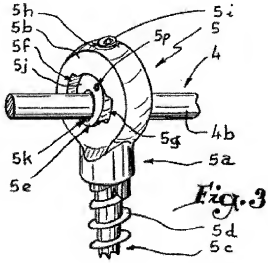
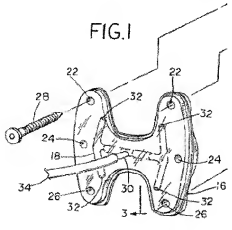


Fig. 3

Stalcup, in turn, discloses a bone plate 10 that generally includes a flexible bag 16, a structural support 18 within the bag and a high strength polymer surrounding the structural support 18 within the bag 16. See Col. 2, lines 22-30 and Figure 1 reproduced below. In Figure 4, Stalcup discloses an embodiment that includes projections and injections tubes 46, 44 that extend from the plate 42. Figure 5 illustrates a similar embodiment that includes projections and injection tubes 66, 64 extending from the plate 62.



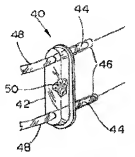


FIG.4

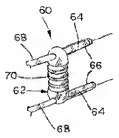


FIG.5

Accordingly, Stalcup discloses a bone plate with a three dimensional geometry that includes projections or structures that extend along a first axis and a second axis.

Nevertheless, the Examiner states that it would have been obvious "to construct the device of Stalcup et al. having at least one screw with an aperture in the head in view of Fournet-Fayard et al. to better secure the interface between the two supports and cross-bar."

A prima facie case of obviousness requires (i) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (ii) a reasonable expectation of success, and (iii) the prior art reference (or references when combined) must teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the

reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *See* M.P.E.P. § 2142.

First, Applicant notes that Claim 26, as amended, recites that the supports extends through the aperture in the bone anchor. Thus, the aperture in the screw is used to secure the support to the bone anchor and does not secure the interface between the supports and cross-bar. Accordingly, at least one element is not taught or suggested by the cited art. .

Moreover, Applicant submits that there is no teaching, suggestion or motivation for modifying and/or combining the references as suggested by the Examiner. That is, the Examiner has not provided a reason that would have prompted a person of ordinary skill in the relevant field to combine and modify Stalcup and Fournet-Fayard as suggested by the Examiner. Instead, the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." See MPEP 2143.01 citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Specifically, the combination suggested by the Examiner would require the plate of Stalcup to extend through an aperture in the head of a bone screw. If possible, this would require a complete rearrangement of the elements disclosed by Stalcup. For example, the modification suggested by the Examiner would require that the support structure and projections to be eliminated and/or modified such that they could be squeezed through, without damage, a small aperture. This would eliminate many of the advantages taught by Stalcup. For example, the projections are porous and allow the polymer to bond with the openings in the spine. The support structure 18, in turn, is used to distribute the polymer within the bag.

Thus, the combination suggested by the Examiner would involve complicated redesign of the plate taught by Stalcup. One of skill in the art would not have a reason to make such radical design changes, which eliminate many of the advantageous features of Stalcup, which teach away from the modifications suggested by the Examiner. The Examiner's argument that the motivation is "having at least one screw with an aperture in the head in view of Fournet-Fayard

et al. to better secure the interface between the two supports and cross-bar" fails to recognize the entire scope of the cited art and the modifications required to meet the limitations of the claimed invention. That is, there is no motivation for completely redesigning the flexible bag of Stalcup so that such that it can be inserted through an aperture of the bone anchor of Fournet-Fayard, which is configured to receive a solid rod. Adding an aperture into the screw head of Stalcup in contrast to the Examiner's position does not appear to better secure the interface between the two supports. Moreover, even if an aperture was randomly added to the screw of Stalcup, neither reference provides a method of installing and inflating the bag through such a screw head with an aperture.

For at least this reason, Applicant suggests that Claim 26, as amended, and Claims 27 and 30-31 are in condition for allowance.

B. The rejection of Claims 28-29 under 35 U.S.C. 103(a) as being unpatentable over the combination of Stalcup et al. '930 and Fournet-Fayard et al. '174 and further in view of Gelbard (U.S. Patent No. 5,397,363).

Claims 28-29, which depend from independent Claim 26, recite additional features not taught by the combination of Stalcup and Fournet-Fayard. Moreover, the combination of Stalcup, Fournet-Fayard and Gelbard does not cure the deficiencies of Stalcup and Fournet-Fayard, as discussed above for Claim 26. For example, the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." See MPEP 2143.01 citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Specifically, the combination suggested by the Examiner would require the plate of Stalcup to extend through an aperture in the head of a bone screw. If possible, this would require a complete rearrangement of the elements disclosed by Stalcup. Accordingly, there is no reason or motivation to combine Stalcup and Fournet-Fayard. Gelbard, which discloses a spinal stabilization system comprising self-tapping screws and a conventional

alignment rod or plate, also does not provide such a motivation. For at least these reasons, Applicant submits that Claims 28-29 are in condition for allowance.

C. The rejection of Claims 33-34 under 35 U.S.C. 103(a) as being unpatentable over the combination of Stalcup et al. '930 and Fournet-Fayard et al. '174 and further in view of Boyce et al. (U.S. Patent No. 5,899,939).

Claims 33-34, which depend from independent Claim 26, recite additional features not taught by the combination of Stalcup and Fournet-Fayard. Moreover, the combination of Stalcup, Fournet-Fayard and Boyce does not cure the deficiencies of Stalcup and Fournet-Fayard, as discussed above for Claim 26. For example, the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." See MPEP 2143.01 citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Specifically, the combination suggested by the Examiner would require the plate of Stalcup to extend through an aperture in the head of a bone screw. If possible, this would require a complete rearrangement of the elements disclosed by Stalcup. Accordingly, there is no reason or motivation to combine Stalcup and Fournet-Fayard. Boyce, which discloses a bone-derived implant, also does not provide such a motivation. For at least these reasons, Applicant submits that Claims 33-34 are in condition for allowance.

D. The rejection of Claim 35 under 35 U.S.C. 103(a) as being unpatentable over the combination of Stalcup et al. '930 and Fournet-Fayard et al. '174 and further in view of Tormala et al. (U.S. Patent No. 5,084,051).

Claims 35, which depends from independent Claim 26, recites additional features not taught by the combination of Stalcup and Fournet-Fayard. Moreover, the combination of Stalcup, Fournet-Fayard and Tormala does not cure the deficiencies of Stalcup and Fournet-Fayard, as discussed above for Claim 26. For example, the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary

reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." See MPEP 2143.01 citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Specifically, the combination suggested by the Examiner would require the plate of Stalcup to extend through an aperture in the head of a bone screw. If possible, this would require a complete rearrangement of the elements disclosed by Stalcup. Accordingly, there is no reason or motivation to combine Stalcup and Fournet-Fayard. Tormala, which discloses a layered surgical biocomposite material, also does not provide such a motivation. For at least these reasons, Applicant submits that Claim 35 is in condition for allowance.

VIII. CLAIMS APPENDIX

Inserted below as a Claims Appendix is a copy of the finally rejected claims in the present case.

1-25. **(Canceled)**

26. A subcutaneously assembled in place orthopedic construct, comprising:

a first bone anchor comprising a distal end and a proximal end, the proximal end including a head with a portal extending therethrough;

a second bone anchor comprising a distal end and a proximal end, the proximal end including a head with a portal extending therethrough;

a first support structure, configured to extend through the portals in the first and second bone anchors;

a second support structure, configured to be attached to the spine; and

a cross bar, which connects the first support structure to the second support structure to form an orthopedic construct;

wherein the cross bar is attached to the first and second support structures subcutaneously; and

wherein at least the cross bar comprises a media that is hardenable while the support structure is positioned within the body of a patient.

27. A subcutaneously assembled in place construct as in Claim 26, wherein the first support structure comprises a hardenable media.

28 A subcutaneously assembled in place construct as in Claim 27, further comprising a first cross tie connecting the cross bar to the first support, and a second cross tie connecting the cross bar to the second support.

29. A subcutaneously assembled in place construct as in Claim 26, further comprising a first cross tie connecting the cross bar to the first support, and a second cross tie connecting the cross bar to the second support.

30. A subcutaneously assembled in place construct as in Claim 26, wherein the cross bar includes a first aperture for receiving the first support, and a second aperture for receiving the second support.

31. **(Canceled)**

32. **(Canceled)**

33. A subcutaneously assembled in place construct as in Claim 26, wherein the hardenable media comprises an epoxy.

34. A subcutaneously assembled in place construct as in Claim 26, wherein the hardenable media comprises polyurethane.

35. A subcutaneously assembled in place construct as in Claim 26, wherein at least the cross bar comprises an outer wall, defining a cavity therein; and a plurality of reinforcing fibers in the cavity.

36-52. **(Canceled)**

IX. EVIDENCE APPENDIX

Appellant is submitting no evidence with this appeal.

X. RELATED PROCEEDINGS APPENDIX

Appellant is unaware of any related appeals or interferences.

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PAT-ABRIEF

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